



Kraft Foods

0098 '00 FEB 16 P3:25

February 15, 2000

FDA / Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: President's Council on Food Safety  
Strategic Planning Task Force  
Draft - Preliminary Food Safety Strategic Plan (December 15, 1999)  
Docket No. 97N-0074

Dear Sir/Madam:

Kraft Foods, Inc. (Kraft) is the leading food manufacturer in the U.S., producing over 7.5 billion individual packages of food a year, with annual sales revenue over \$17 billion. Whether regulated by the Food Safety and Inspection Services (FSIS) or the Food and Drug Administration (FDA), these products are sold under well-known brand names -- such as Oscar Mayer, Kraft, Maxwell House, and Post -- that are found in almost every American home. The safety of our products and corresponding integrity of our brands are of paramount importance to Kraft. Accordingly, Kraft has a very substantial interest in the implementation of safety standards and programs, including the application of the hazard analysis and critical control point (HACCP) system across the food supply chain.

Kraft appreciates the opportunity to comment on the President's Council on Food Safety Strategic Plan. Kraft fully supports and has implemented quality and food safety systems and practices that protect consumers.

**Science and Risk Assessment**

Kraft fully supports the objectives in this section. We view the plan as an opportunity to foster a proactive partnership between the regulatory agency, industry, academia, and consumers based on the common element of sound science. We agree that all future regulatory activity must be based on science and risk assessment. A focused approach based on priorities selected via risk assessment makes sense from both a scientific as well as resource perspective.

**Risk Management**

Kraft recognizes its role in effectively managing food safety as a leading producer of food and beverages. We fully support harmonization between state and federal programs and across agencies and the development and implementation of preventative techniques and controls using risk based approaches. We support the objective of improving rigor and clarity through the establishment of national standards.

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We support the concept of surveillance as a means of rapid identification and response to potential food safety issues. We would recommend more efficient inspection and regulation within the scope of the government's existing authority. Targeted focus on results of rigorous risk assessment should allow a reduction of resources focused on inspection with no negative impact on consumer protection.

Environmental microbiological monitoring is the best currently available tool for verifying sanitation program effectiveness, employee practices, and elimination of potential harborage sites. Results can be used to diagnose the need for additional preventative measures.

Although finished product testing can play a role in process validation, finished product testing is of limited value as a routine verification tool, due to the large number of test samples required for statistical significance and the inherent error rate. If excellent controls are in place, the defect level should be very low and therefore, the sample size for each lot must be large to be statistically significant. For example, to detect a low level of *Listeria monocytogenes*, such as 1%, the sample size must be 300 or greater per lot to achieve 95% confidence that the microorganism will be found. Even at rates of 2.4%, 4.4%, and 5.7%, the incidence rates referenced in the May 26, 1999 FSIS notice, samples size per lot would need to be 124, 67, 52, respectively, to detect it with 95% confidence.

Moreover, finished product testing is not a substitute for adequate control procedures and does not provide the diagnostic information necessary to correct a problem, if one exists. Effective programs do not necessarily require product testing as finished product testing has limited utility even as a verification tool.<sup>1</sup> Therefore, finished product testing should not be the highest priority for establishments with limited resources. Establishments with limited resources should focus, as stated previously, on environmental monitoring.

Due to the error rates inherent in laboratory testing, which in some laboratories can be greater than the actual incidence rate, a mechanism must be developed to address retesting or confirmation of an initial positive product result, particularly in the absence of other supporting data. In addition, the zero tolerance standard means that any laboratory error will have significant consequences. Therefore, laboratory practices must be maintained at the highest possible standards and a mechanism for confirmation of results must be available. We urge government and industry to adopt laboratory standards and practices as recommended by the Food Laboratory Accreditation Working Group and administered by the Association of Official Analytical Chemists.<sup>2</sup>

Where scientific uncertainty exists, government requirements should be based on the best science available. We urge the government to recognize the cost, not just in monetary terms, but in loss of focus on important food safety issues of rules that are not based on sound science. The establishment of all standards must be transparent and grounded in sound science. Where data gaps exist, we should fund research programs to identify and develop technologies to reduce and/or eliminate the hazard. The attainable goal of reasonable certainty of no harm should be the foundation of all underlying risk assessment and regulation.

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<sup>1</sup>Tompkin, et al "Guidelines to Prevent Post Processing Contamination From *Listeria Monocytogenes*" Dairy, Food and Environmental Sanitation (in press)

<sup>2</sup>AOAC International, "Food Laboratory Accreditation Gets Specific: From ISO 9002 to ISO 25 to FLAWG" *Inside Laboratory Management*, February 1998

We agree that positive approaches to food safety are far more effective in the long-run and should be the primary focus of a long-term strategic plan. We support the themes of:

- voluntary approaches to improving food safety (i.e., promote voluntary "best practices")
- promotion of the development and commercialization of new technologies
- development of "state of the art" science-based education and training programs "from farm to table"
- use of incentive programs

Finally, all stakeholders, including industry need rapid access to data and information about hazards and outbreaks when they occur, including access to critical technical data currently held in confidence within governmental agencies.

#### Risk Communication

From farm to table, food safety is everyone's responsibility. We recognize the delicate balance of communicating preventive food safety measures and alerting the public to potential risks, while maintaining consumer confidence in the food supply -- which is still the safest in the world. Government needs to work in partnership with industry, scientific and public health professionals and other government agencies responsible for public health to strengthen ongoing food safety education throughout the supply chain. Wherever possible, the government should build on current educational programs such as Fight Back!, at the same time making sure that messages and communication channels are effectively tailored for each audience.

Medical experts agree that the risk of foodborne illness in generally healthy adults is rare, but certain individuals have a higher risk -- pregnant women, older adults and those with weakened immune systems. In addition to ongoing preventive education for the general public, it is critical to continue and enhance educational efforts targeted to individuals who are at an increased risk of developing listeriosis, along with medical and public health professionals who reach these susceptible populations.

#### Summary

Kraft supports the President's Council's draft strategic plan and continued efforts to ensure regulation for continued improvement in the safety of the nation's food supply. We reiterate our belief in the precept of science-based regulation and food safety systems. Further, we support risk communication that educates and informs the public, ensuring their continued confidence in the nation's food safety system. We support efforts to enhance coordination and utilization of government resources, as well as coordination of food safety research without the creation of more bureaucratic structure.

Kraft offers these comments as part of our commitment to work cooperatively with government, consumers, science, and industry to achieve the vision and goal set forth by the Council.

Respectfully Submitted,



Jean Spence

Vice President, Kraft Foods

Worldwide Quality & Scientific Relations

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